



**Johns Manville**

*A Berkshire Hathaway Company*

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**VIA E-MAIL AND OVERNIGHT MAIL**

June 7, 2010

Dr. Ruth Lunn  
Director, Report on Carcinogens  
National Toxicology Program  
National Institute of Environmental Health Sciences  
MD KY-14  
530 Davis Drive  
Morrisville, NC 27560

Re: *Comments of Johns Manville on "Draft Substance Profile: Glass Wool  
Fibers (Respirable) as a Class"*

Dear Dr. Lunn:

Thank you for the opportunity to comment on the "*Draft Substance Profile: Glass Wool Fibers (Respirable) as a Class*"<sup>1</sup> (Draft Profile). Johns Manville (JM) manufactures a variety of glass fibers including insulation glass wool, special purpose glass fibers (SPF), and glass reinforcement fibers.<sup>2</sup> JM is also a member of the North American Insulation Manufacturers Association (NAIMA) and we endorse the NAIMA comments submitted on the Draft Profile.

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<sup>1</sup> <http://ntp.niehs.nih.gov/NTP/RoC/twelfth/2010/DraftSubProfiles/GWF20100421.pdf>

<sup>2</sup> Johns Manville, a Berkshire Hathaway company, is a leading manufacturer and marketer of premium-quality products for building insulation, mechanical insulation, commercial roofing, and roof insulation, as well as fibers and nonwovens for commercial, industrial, and residential applications. JM serves markets that include aerospace, automotive and transportation, air handling, appliance, HVAC, pipe and equipment, filtration, waterproofing, building, flooring, interiors, and wind energy. In business since 1858, the Denver-based company has annual sales of approximately \$2 billion and holds leadership positions in all of the key markets that it serves. JM employs approximately 6,500 people and operates 41 manufacturing facilities in North America, Europe and China. Additional information can be found at [www.jm.com](http://www.jm.com).

JM is the only member of NAIMA still making SPF. JM's SPF are made primarily for high efficiency filtration and battery separator media applications. JM submitted comments on the 2009 Glass Wool Draft Background Document<sup>3</sup> entitled "*Johns Manville Commentary on NTP Draft Background Document for Glass Wool Fibers: Special Purpose Fibers and Hazard Classification.*"<sup>4</sup> Those comments described how SPF are distinguished from insulation glass wools. Specifically, JM stated then that:

. . . it is fiber durability that we believe provides the key critical difference in distinguishing glass wool insulation fibers from special purpose fibers for purposes of hazard determination.<sup>5</sup>

JM also submitted live testimony at the June 8 – 9, 2009 meeting of the Glass Wool Expert Panel (Expert Panel).<sup>6</sup>

JM is disappointed that the Draft Profile did not fully follow the unanimous recommendation of the Expert Panel to delist the more biosoluble insulation glass wool fibers and to retain at "reasonably anticipated" status in the Report on Carcinogens (RoC) only those "special purpose fibers of concern."<sup>7</sup> Those latter fibers, which comprise only one percent of all glass fibers manufactured today, were defined as: glass fibers with the physical characteristics as follows - longer, thinner, less soluble fibers (for example,  $\geq 15$   $\mu\text{m}$  length with a  $k_{\text{dis}}$  of  $\leq 100$   $\text{ng}/\text{cm}^2/\text{h}$ ).<sup>8</sup> The comments submitted by NAIMA and others describe in detail the great weight of scientific evidence supporting the Expert Panel's recommendation.

As described in the comments submitted by NAIMA as well as in the comments submitted on behalf of NAIMA Canada by Dr. Thomas Hesterberg, advancements in glass fiber toxicology have afforded manufacturers the opportunity to move to more biosoluble – and hence safer – fibers. As stated in JM's comments on the draft Background Document:

It is also important to note that JM is not developing any new durable special purpose fibers; to the contrary, newly-developed biosoluble fibers (*i.e.*, fibers whose biosolubility is in the range of, or greater than, MMVF 10 and MMVF 11) are beginning to replace JM special purpose fibers commercially for some applications.<sup>9</sup>

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<sup>3</sup> <http://ntp.niehs.nih.gov/ntp/roc/2009/November/Background/FormaldehydeDraftBackgroundDocument.pdf>

<sup>4</sup> <http://ntp.niehs.nih.gov/ntp/roc/twelfth/2009/june/Bauer20090522.pdf>

<sup>5</sup> *Id.* at page 4.

<sup>6</sup> <http://ntp.niehs.nih.gov/ntp/roc/twelfth/2009/june/Agenda.pdf>

<sup>7</sup> [http://ntp.niehs.nih.gov/Ntp/roc/twelfth/2009/june/GWF\\_PartB.pdf](http://ntp.niehs.nih.gov/Ntp/roc/twelfth/2009/june/GWF_PartB.pdf).

<sup>8</sup> *Id.* at page 1.

<sup>9</sup> <http://ntp.niehs.nih.gov/ntp/roc/twelfth/2009/june/Bauer20090522.pdf> at page 3.

For example, JM has formulated a biosoluble alternative to the more durable JM 475 special purpose fiber that was tested extensively in the chronic animal inhalation studies. In 2006 JM sent samples of the 481 fiber to the Fraunhofer Institute in Hanover, Germany to be tested according to both EU and German protocols. As can be seen in the enclosed copy of the certified results, JM 481 passes both the EU and German protocols and is not required to be labeled as a carcinogen in the EU. Thus, JM 481 offers filtration products manufacturers the ability to choose a fiber media that meets all the performance criteria for high efficiency filtration with the extra margin of safety provided by a biosoluble fiber.

It is important to note that critical parts of the Draft Profile are consistent with the Expert Panel's work and the weight of scientific evidence. Thus, the Draft Profile states the following:

Carcinogenicity within the class of respirable glass wool fibers varies, and not all fibers within this class cause cancer. A spectrum of responses was observed in experimental animal studies; for example, some glass wool fibers were carcinogenic by several routes of exposure, including inhalation; some were carcinogenic only by routes of exposure other than inhalation; and some were not carcinogenic in any studies.<sup>10</sup>

The real issue at hand is how to differentiate between glass fibers that were not carcinogenic and those that did show a carcinogenic hazard in animal studies and that are appropriately classified as "reasonably anticipated." JM agrees with the Draft Profile that the carcinogenicity of individual glass wool fibers can be evaluated on a case-by-case basis and JM has conducted various tests on every JM fiber. The challenge is to ensure that the final Substance Profile is made more clear so that it can provide complete, accurate and actionable data and information.

The final Substance Profile should not (and legally likely cannot) classify as "reasonably anticipated" all glass wool fibers ("as a class") including the vast majority of fibers that were not carcinogenic in relevant animal studies. This is explained in detail in the NAJMA comments.

But classifying all glass wool fibers as potential carcinogens would also have the following serious unintended negative consequences for industry, the government agencies tasked with regulating glass fibers and the public:

(1) a message will be sent to all of industry (not just the glass fiber industry) not to invest in high-quality health studies, because they may be ignored;

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<sup>10</sup> <http://ntp.niehs.nih.gov/NTP/RoC/twelfth/2010/DraftSubProfiles/GWF20100421.pdf> at page 1.

(2) a decision to lump the more-biosoluble glass fibers with biodurable fibers and classify them all as potential carcinogens diminishes the incentives to manufacture fibers that are less biodurable and safer; and,

(3), – most importantly – classifying all glass wool fibers as potentially carcinogenic sends a strong (and incorrect) signal that biosoluble fibers have the same hazard as biodurable fibers, a result that is not only scientifically incorrect and would lead to inappropriate product selection decisions but also a result that is anathema to the mission of the NTP.

For foregoing reasons, we strongly urge the NTP to more clearly classify glass fibers by differentiating between the biosoluble insulation wool fibers and the more durable special purpose fibers of concern. Only the latter fibers should be listed in the RoC as “reasonably anticipated.” Such differentiation of glass fibers by actual carcinogen hazard classification is consistent with both the glass fiber classification by IARC<sup>11</sup> and other authoritative scientific bodies as well as NTP’s own 2009 Expert Panel.

Sincerely,

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Bruce D. Ray  
Director of Governmental and Regulatory Affairs

Enclosure

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<sup>11</sup> IARC *Monographs on the Evaluation of Carcinogenic Risks to Humans*, Man-made Vitreous Fibres, Volume 81 (2002). <http://monographs.iarc.fr/ENG/Monographs/vol81/index.php>



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Hannover,  
January 19, 2007

## Certificate

The biopersistence of the fibre type MMVF48 (JM481) was investigated after intratracheal instillation within the following study:

Fraunhofer ITEM study no.: 02G06015

Test substance: MMVF48 (JM481)

Sponsor: Johns Manville, USA

Title: The Biopersistence of Man-Made Vitreous Fibre (MMVF) MMVF48 in Rats after Intratracheal Instillation

This animal study was conducted in compliance with the Principles of Good Laboratory Practice (German Chemicals Law § 19a Appendix 1 pp. 2119-2129, June 28, 2002). The protocol of the European Commission (ECB/TM 27 Rev. 7, 1998) with slight changes according study protocol was followed.

The treatment of rats was performed in July 2006 by intratracheal instillation of a total dose of 2 mg per rat. The fibre retention data of sacrifice dates up to 3 months after instillation were used for analysis.

**Following halftimes were calculated by the method according to the protocol of the European Commission:**

**WHO fibre fraction ( $L > 5 \mu\text{m}$ ,  $D < 3 \mu\text{m}$ ,  $L/D > 3/1$ ): 38 Days**

According to Appendix IV Nr.22 of the German Gefahrstoffverordnung (Dangerous Substances Act, Revision date December 23, 2004) for using MMVF for heat and sound insulation in building construction in Germany the half-time of the WHO fibre fraction should be less or equal to 40 days.

**Long fibres fraction (length  $> 20 \mu\text{m}$ ): 26 Days**

According to Directive 67/548/EEC (revised by guideline 97/69/EG of the Commission dated December 5, 1997) Note Q the classification as carcinogenic material is not applicable for mineral wools if the halftime for fibres longer than  $20 \mu\text{m}$  is less than 40 days in the biopersistence test by intratracheal instillation.

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Prof. Dr. Uwe Heinrich  
Executive director of Fraunhofer ITEM

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Dr. Bernd Bellmann  
Study director